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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/944,175 | 09/04/2001 | Nobuhiko Ogura | Q65952 | 9850 |

7590 05/03/2004

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| EXAMINER |
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TRAN, MY CHAU T

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| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

214.

Office Action Summary

Application No.

09/944,175

Applicant(s)

OGURA, NOBUHIKO

Examiner

MY-CHAU T TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 10-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/8/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/04 has been entered.

Status of Claims

2. Applicant's amendment filed 1/12/04 is acknowledged and entered. Claims 3 and 9 have been canceled. Claims 1, 4, 10-11, and 22 have been amended.
3. Claims 23-41 are canceled by the amendment filed on 12/4/02.
4. Claims 1-2, 4-8, and 10-22 are pending.
5. This application claims priority to a foreign application, Japan 2000-267449, filed 9/4/00.
6. The information disclosure statement (IDS) submitted by applicant filed on 1/8/04 is acknowledged and considered as noted on PTO-1449.

Withdrawn Rejections

7. In view of applicant's amendment of claim 1 and cancellation of claims 3 and 9, the rejection of claim 1-8, 12-18, and 22 under 35 USC 102(b) as anticipated by Ullman et al. (US Patent 6,103,537) has been withdrawn.
8. In view of applicant's amendment of claim 1 and cancellation of claims 3 and 9, the rejection of claims 1-2 and 9-21 under 35 USC 103(a) as being obvious over Alfenito (US Patent 6,355,419 B1) in view of Ichie (US Patent 5,796,112) has been withdrawn.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2, 4-6, and 10-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mosaic Technologies ("Mosaic") (WO 98/51,823).

Mosaic discloses several methods of analyzing target molecules that specifically binds to the nucleic acid probes, which are immobilized to an electrophoretic medium by electrophoresis (pg. 3, lines 8-30). The electrophoretic medium comprises a matrix (substrate). The capture probes are immobilized (spotted) to the matrix in several different formats such as a one-dimensional array, two-dimensional array, and three-dimensional array (pgs. 22-24). In general

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method comprises 1) immobilizing capture probes to the matrix wherein the probe specifically bind to the target molecule and demonstrate the presence or absence of the target molecule (pg. 5, lines 28-32; pg. 13, line 29 to pg. 14, line 3) (refers to fixing probes in advance on a substrate); 2) binding the target molecules to the capture probes (pg. 5, lines 28-32; pg. 25, lines 15-21) (refers to binding the target with the probe); 3) electrophoresing the non-target molecule out of the matrix (pg. 25, lines 21-26) (refers to fractioning the captured target); and 4) detecting the immobilized target molecule bound to the capture probe by a label such as fluorescent or chemiluminescent label (pg. 29, lines 15-22). The target can be labeled prior to binding to the capture probe (pg. 30, lines 20-29) or after the target is fractionated (pg. 30, lines 30-34). Additionally, the detectable signals are optically detected by optically scanning the arrays such as a one-dimensional array, two-dimensional array, and three-dimensional array (pg. 31, line 15 to pg. 32, line 14) (refers to quantitative analysis of the detected target). Thus the method of Mosaic anticipates the presently claimed method.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-2, 4-8, and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosaic Technologies ("Mosaic") (WO 98/51,823) and Briggs et al. (US Patent 5,560,811).

Mosaic discloses several methods of analyzing target molecules that specifically binds to the nucleic acid probes, which are immobilized to an electrophoretic medium by electrophoresis (pg. 3, lines 8-30). The electrophoretic medium comprises a matrix (substrate). The capture probes are immobilized (spotted) to the matrix in several different formats such as a one-dimensional array, two-dimensional array, and three-dimensional array (pgs. 22-24). In general method comprises 1) immobilizing capture probes to the matrix wherein the probe specifically bind to the target molecule and demonstrate the presence or absence of the target molecule (pg. 5, lines 28-32; pg. 13, line 29 to pg. 14, line 3) (refers to fixing probes in advance on a substrate); 2) binding the target molecules to the capture probes (pg. 5, lines 28-32; pg. 25, lines 15-21) (refers to binding the target with the probe); 3) electrophoresing the non-target molecule out of the matrix (pg. 25, lines 21-26) (refers to fractioning the captured target); and 4) detecting the immobilized target molecule bound to the capture probe by a label such as fluorescent or chemiluminescent label (pg. 29, lines 15-22). The target can be labeled prior to binding to the capture probe (pg. 30, lines 20-29) or after the target is fractionated (pg. 30, lines 30-34).

Additionally, the detectable signals are optically detected by optically scanning the arrays such

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as a one-dimensional array, two-dimensional array, and three-dimensional array (pg. 31, line 15 to pg. 32, line 14) (refers to quantitative analysis of the detected target).

The method of Mosaic does not expressly disclose the step wherein the targets are electrophoresed in a plurality of capillaries.

Briggs et al. disclose a method of multiplexing electrophoresis analysis with an array of capillary electrophoresis columns (Abstract; col. 3, line 66 to col. 4, line 3; fig. 4C). The method comprises using fluorescence detection of target species in capillary electrophoresis (col. 1, line 66 to col. 2, line 11; col. 15, lines 6-46).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the step wherein the targets are electrophoresed in a plurality of capillaries as taught by Briggs et al. in the method of Mosaic. One of ordinary skill in the art would have been motivated to include the step wherein the targets are electrophoresed in a plurality of capillaries in the method of Mosaic for the advantage of providing a binding assay system wherein multiple samples can be analyzed in parallel and uses small volumes (Briggs: col. 6, line 66 to col. 7, line 9) since both Mosaic and Briggs et al. disclose the method of fluorescence detection of target species by capillary electrophoresis (Mosaic: pg. 8, lines 30-34, and pg. 29, lines 15-22; Brigg: col. 1, line 66 to col. 2, line 11). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Mosaic and Briggs et al. because the method of Mosaic would need no modification other than increasing the number of capillaries in order to electrophorese the targets, would not materially affect the method steps.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
April 26, 2004


PADMASHRI PONNALURI
PRIMARY EXAMINER